# CENTER FOR DRUG EVALUATION AND RESEARCH

# APPLICATION NUMBER: 75-702

# **APPROVED DRAFT LABELING**



LABELING HFD-613 OGD
MDA NO. 20-462 FCD 2-14-27
REVIEWED BY 000 2-22-99

Safety Seal® is broken or continued with

# ACTIVE INCREDIENT: Cromotory Sodium: Nasal Alterey Symptom Controls

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Nasalcrom Nasal Spray PURPOSE: Nasal Altergy Symptom Controller

To prevent and relieve hasal symptoms of hay fever and other hasal altergies: altergic sturfy nose. unny/itchy nose sneezing

Dh:EChuffs:

Adults and children 6 years of age and older:

- Spray once into each nostrill Repeat 3-4 times a day levery 4-6 hours). if needed, may be used up to 6 times a day. See side panel on how
- Use every day while in contact with the cause of your allergies tpollens, to use pump. molds, pets, and dust).
- To prevent nasal allergy symptoms, use before contact with the cause of your allergies. For best results, start using up to one week perore contact.
- mif desired, you can use Nasalcrom with other medicines, including other allergy medicines.

Children under 6 years of age: Do not use unless directed by a doctor

WARNINGS:

### Aik à doctor ablore use il you naver

- Discolored hasal discharge.
- E Sinús pain.
- w wheezing

### When using this product

- It may take several days of use to notice an effect. Your best effect may not be seen for 1 to 2 weeks.
- Brief stinging or sneezing may occur right after use
- Do not use this product to treat sinus infection, asthma, or cold symptoms
- Do not share this bottle with anyone else as this may spread germs.

### stop using this groduct live and the same of the same

- w Your symptoms worsen.
- You have new symptoms.
- Your symptoms do not begin to improve within two weeks.

See your doctor because these could be signs of a serious illness.

As with any drug, if you are pregnant or nursing a baby, seek the advice of a health-care professional before using this product. keep this and all drugs out of the reach of children. In case of accidental ingestion/overdose, seek professional assistance of contact a Poison Control Center immediately

Do not use If printed plastic bottle wrap imprinted with "Safety Sealo" is broken or missing.



## Nasalcrom®

any medication read all label directions. Keep carton and package insert. They contain im-portant instructions.

#### How to Use the Pump Spray:

- 1. Blow your nose before using Nasalcrom.
- 2. Remove the clear plastic cap and yellow safety clip.
- 3. Hold pump with thurib at bottom and nozzle between fingers. If this is the first time you are using the pump, spray 5 times into the air or until you get a fine mist. If you have not used the pump for 14 days, spray 2 times into the air before using again.
- 4. Hold bottle as snown in picture. Insert nozzle into nostril Spray upward while breath. ing in through the nose.
- Repeat in other nostril. 5. To keep clean, wipe the nozzie Put clear plastic cap and yellow safety clip back on the bottle.
- 6. Do not share this bottle with anyone else as this may spread germs.

Store between 15°-30° C (59°-86° F). Keep away from light,

INCREDIENTS: Each mt. Con-lains 40 mg cromolyn sodium In purified water with 0.01% benzalkonlum chioride 10 pre-serve and 0.01% EDTA (ede-tate disodium) to stublize the

# Nasal Spray

Nasal Spray

cromolyn sodium nasal solution USP

Nasal Allergy Symptom Controller

### Prevents and relieves nasal allergy symptoms:

- runny/itchy nose
- sneezing
- allergic stuffy nose

### Without Drowsiness

Now Available Without a Prescription

**200** METERED SPRAYS Each spray delivers 5.2 mg cromolyn sodium

0.88 FL. OZ. (26mL)



### Nasalcrom<sup>®</sup>

what makes Nasalcrom unique?

- Prevention and relief. Nasalcrom can relieve your nasal allergy symptoms and, if used as directed, can also prevent your symptoms.
- Non-drowsy. Many allergy medications contain antinistamines. which may cause drowsiness. Nasalcrom's unique formula works only in your nose and you don't get drowsy.
- Builds protection. Nasatcrom works by build-Ing protection against your nasal allergy symptoms. To maintain protection. continue to use Nasalcrom dally.
- Can be used every day you need its protection. Nasalcrom is a gentle nasal spray that works differ ently from decongestant sprays Unlike those products, it continues to be safe and effective when used every day.
- Can be used with other medications. Nasaicrom can be used safely with other medications, including other allergy medications.

1 If you have any questions or comments, call 1-800-962-5357. DISTRIBUTED BY

#### McNEIL

MENEIL CONSUMER PRODUCTS CO. DIVISION OF MONEIL - PPC, INC FORT WASHINGTON, PA 19034 USA Active ingredient made in the United Kingdom Final drug product made in France 60 McN-PPC, Inc. 1997

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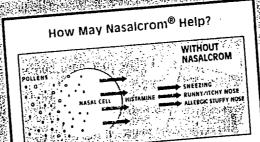
## Nasal Allergy Symptom Prevention and Relief

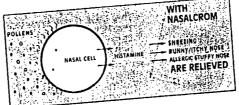
What Causes Nasal Allergy Symptoms?

Nasal allergies are caused by airborne pollens from trees, grasses or ragweed, and by molds, animals and dust. Exposure to these nasal allergy-causing substances may cause cells in your nose to release a substance called histamine. When histamine is released it causes nasal allergy symptoms: sneezing, runny/itchy nose, and allergic stuffy nose.

### How Are Nasal Allergies Different From The Common Cold?

Some nasal allergy symptoms may seem like cold symptoms. But colds are caused by viral infections, and symptoms often include fever, hody aches, discolored nasal discharge. or cough. It's rare for nasal allergies to produce these symptoms. If you have them, please call your doctor to see if Nasalcrom is right for you.





Nasalcrom's unique formula works directly on the allergy sensitive cells in your nose to protect them from substances like pollens. Nasalcrom reduces the release of histamine, helping to decrease the allergic reaction before it starts. And with regular use, you get more protection.

To help prevent symptoms, start using. Nasalcrom one week before contact with the cause of your nasal allergies.

Nasalcrom works here



# What Makes Nasalcrom® Unique?

- 1. Prevention and relief. Nasalcrom can relieve your nasal allergy symptoms and, if used as directed, can also prevent your symptoms.
- 2. Non-drowsy. Many allergy medications contain antihistamines, which may cause drowsiness. Nasalcrom's unique formula works only in your nose and you don't get drowsy.
  - Builds protection. Nasalcrom works by building protection against your nasal allergy symptoms. To maintain protection, continue to use Nasalcrom daily.
- 4. Can be used every day you need its protection. Nasalcrom is a gentle nasal spray that works differently from decongestant sprays. Unlike those products, it continues to be safe and effective when used every day
- 5. Can be used with other medications. Nasalcrom can be used safely with other medications, including other allergy medications.

#### How To Use Nasalcrom<sup>®</sup> Most Effectively

Nasalcrom works best at preventing your nasal allergy symptoms if you begin using it before your symptoms start.

- For best results for prevention, start, using Nasalcrom one week before contact, with the cause of your allergies. For example, if you have hay fever, start using Nasalcrom one week before your peak nasal allergy season begins and use it every day throughout your season.
- To prevent symptoms from coming back, it is important to continue to use Nasalcrom every day while in contact with the cause of your nasal allergies, even when you are free of symptoms.
- NOTE: It may take several days of use to notice an effect. You may not get the full effect for 1-2 weeks. It is important to continue using Nasalcrom regularly.
- You should stop using flavalerom if you don't get relief within 2 weeks.
- If you need to use Masalcrom for longer than 12 weeks, ask your doctor.
- Some people may get brief nasal stinging and/or sneezing right after the use of Nasalcrom.

Nasalcrom can be used every day. Doctors have prescribed it to millions of allergy sufferers to help control their nasal allergy symptoms.

### How To Use The Pump Spray



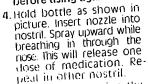
1. Blow your nose before using Nasalcrom.

2. Remove the clear plastic cap and yellow safety clip.



3. Hold pump with thumb at bottom and nożzle between fingers. If this is the first time you are using the pump, spray 5 times into the air or until you get a fine mist. If you have not used the pump for 14 days, spray 2 times into the air before using again.

1300



- 5. to keep clean, wipe the no. de. Put clear plastic cap and yellow safety dip tack on the bottle.
- 6.Do not share this bottle with anyone else as this may spread germs.

Some people may get brief nasal stinging and/or sneezing right after the use of Misalcrom.

### Nasal Allergy-Controlling Tips

- Many people are allergic to the dust mites that live in carpeting and bedding. Put mattresses and pillows in airtight covers and, if practical, get rid of all carpets. Use an air purifier with a HEPA (High Efficiency Particulate Air) filter to clean the air.
- People with nasal allergies to animals should limit their contact with these animals. It is the animal's dander (skin flakes) that causes allergies, not the hair length.
- People who are allergic to pollen and mold should use an air conditioner as much as possible. When you open the windows in your house, you let in pollen and mold spores.

Ask your doctor or health-care professional for more tips on how to allergy-proof your home.

if you have any questions about Nasalcrom<sup>®</sup> Nasal Spray please call:

1-800-962-5357

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Monet Consumer Products Co.

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Active Ingredient (per sprey) Purpose
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Questions? Call toll-free 1-800-323-0000

Manufactured by EAUSCH & LOSS

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Other Information # store between 20"- 25°C (68"- 77"F) Institute ingredients, be altonium charide, edetate disorbum, purified water

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Manufactured by BAUSCH & LONG Pharmaceuticals, Inc Tampa, FL 33637

NOC 57787-397-76

Cromolyn Sodium Nasal Solution USP

**NASAL SPRAY** Nasal Allergy Symptom Controller

For introduced use only. See carino and package insart for full product information.

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Active ingredient (per spray)

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Questions? Call toll-free 1-800-323-0000

Manufactured by SAUSCH & LONGS Pharmaceuticals, Inc. Tampa, FL 33637



NOC 57/102-397-26

#### Cromolyn **Sodium Nasal** Solution USP MASALSPRAY

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for full product information.

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CORE E798769 2 36" x 1 3/4" 56" Non UV at left 1/16" blergime 26 mt. LASEL Ant le et 100% 4 Cotor: Brack, Pate 125, Pate 256 & Pate 466 L-1917 PHARMACODE 6

NO DROWSINESS - NO JITTERS - NOW HART FORMING
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Other information (1997)

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Questions? Call toll-free 1-800-323-0000

Manufactured by BAUSCH & LOSS
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Tampa, FL 33637
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🎉 HealthGuard®

NDC 57782-397-26

#### Cromolyn Sodium Nasal **Solution USP**

NASAL SPRAY Nasal Aller by Symptom Controller

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### YARAS JASAN

### **42U** noitulo2 leseM Cromolyn Sodium

#### **Cromolyn Sodium Nasal Solution USP NASAL SPRAY**

(Adults and children 2 years and older)

#### Drug Facts

Active ingredient (per spray) Cromolyn sodium 5.2 mg..

Purpose

.Nasal allergy symptom controller

Uses to prevent and relieve nasal symptoms of hay fever and other nasal allergies: runny/itchy nose sneezing allergic stuffy nose

#### Warnings

Do not use if you are allergic to any of the ingredients

Ask a doctor before use if you have

■ fever ■ discolored nasal discharge ■ sinus pain ■ wheezing

#### When using this product

- it may take several days of use to notice an effect. Your best effect may not be seen for 1 to 2 weeks.
- brief stinging or sneezing may occur right after use
- do not use it to treat sinus infection, asthma, or cold symptoms
- do not share this bottle with anyone else as this may spread germs

#### Stop use and ask a doctor if

- shortness of breath, wheezing, or chest tightness occurs
- m hives or swelling of the mouth or throat occurs
- your symptoms worsen
- you have new symptoms
- your symptoms do not begin to improve within two weeks
- you need to use for more than 12 weeks

If pregnant or breast feeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

#### Directions = see package insert on how to use pump

- parent or care provider must supervise the use of this product by young children adults and children 2 years and older:
- spray once into each nostril. Repeat 3-4 times a day (every 4-6 hours). If needed, may be used up to 6 times a day.
- use every day while in contact with the cause of your allergies (pollen, molds, pets, and dust)
- to prevent nasal allergy symptoms, use before contact with the cause of your allergies. For best results, start using up to one week before contact.
- if desired, you can use this product with other medicines, including other allergy medicines.
- Children under 2 years: Do not use unless directed by a doctor.

#### Other information

- store between 20°- 25°C (68°- 77°F)
- protect from light
- keep carton and package insert. They contain important

Drug Facts (continued)

Inactive ingredients benzalkonium chloride, edetate disodium, purified water

Questions? call toll-free 1-800-323-0000

Before using any medication read all label directions. Keen carton and package insert. They contain important information.





Cromolyn Sodium Nasal Solution is convenient and easy to administer using the metered spray pump. See package insert for spray pump directions.

> USE ONLY IF BODY SEAL IMPRINTED WITH "Protective Seal" AND YELLOW - IS INTACT.

Manufactured by **BAUSCH & LOMB** Pharmaceuticals, Inc. Tampa, FL 33637 HealthGuard is a registered trademark of Bausch & Lomb Pharmaceuticals, Inc. ©Bausch & Lomb Pharmaceuticals, Inc.



NDC 57782-397-26

# Cromolyn **Sodium Nasal Solution USP**

**NASAL SPRAY** 

Nasal Allergy Symptom Controller

Prevents and Relieves Nasal Allergy Symptoms:

■ runny/itchy nose

sneezing

■ allergic stuffy nose

### Without Drowsiness

**Full Prescription Strenath** 

Safe For Ages 2 Years & Older

### **200** Metered Sprays

Each spray delivers 5.2 mg cromolyn sodium

0.88 FL OZ (26 mL)

#### WHAT MAKES CROMOLYN SODIUM NASAL SOLUTION UNIQUE?

#### Nasai Allergy Symptom Prevention

Cromolyn Sodium Nasal Solution can prevent nasal allergy symptoms when used before exposure to the cause of your nasal allergies, and will build protection against future symptoms as long as you continue to use Cromolyn Sodium Nasal Solution as directed.

#### **Effective Relief**

Cromolyn Sodium Nasal Solution provides original prescriptionstrength relief of nasal allergy symptoms, including congestion, sneezing and runny or itchy nose.

#### Works Only In Your Nose

Cromolyn Sodium Nasal Solution is a nasal spray that works only in your nose - where nasal allergens attack. It helps to stop the cells in your nose from reacting to pollen, pet dander, and other allergens, so you don't experience nasal allergy symptoms.

#### SAFE

- No drowsiness
- No jitters
- No "rebound" nasal congestion
- Non habit forming
- · Safe to use with other medicines, including other allergy medicines
- · Safe to use throughout your allergy season
- · Good for year-round allergies
- . Safe for children as young as two years old

ET39753 XQ91303 REV.6/01-03 FDA4

# STOP AFTER 2 WEEKS IF YOU DON'T GET ANY RELIEF

STOP USE AND ASK DOCTOR if

shortness of breath, wheezing, chest tightness, hives, or swelling of the mouth or throat occurs while using this product. You may be allergic to Cromolyn Sodium Nasal Solution and require further medical attention.

Do not use Cromolyn Sodium Nasal Solution if allergic to any of its ingredients.



1.



2.



#### **SPRAY PUMP DIRECTIONS**

#### For Adults and Older Children

Blow your nose before using Cromolyn Sodium Nasal Solution.

- 1. Remove the plastic cap and safety clip (picture 1).
- 2. Hold the pump with thumb at bottom and the nozzle between fingers. If this is the first time you are using the pump, or if you have not used the pump for several days, spray in the air until you get a fine mist (picture 2).
- 3. Hold the bottle as shown in the picture. Insert nozzle into nostril. Spray upward while breathing in through the nose. This will release one dose of medication. Repeat in other nostril. Some people may get brief stinging and/or sneezing right after the use of Cromolyn Sodium Nasal Solution (picture 3).
- 4. To keep clean, wipe the nozzle. Put plastic cap and safety clip back on the bottle.
- 5. Do not share this bottle with anyone else as this may spread germs.

#### For Very Young Children

- 1. Only an adult should administer the product.
- 2. Use care when inserting the nozzle into the nose to avoid injury.

#### NASAL ALLERGY CONTROLLING TIPS

Many people are allergic to the dust mites that live in carpeting and bedding. Put mattresses and pillows in airtight covers and, if practical, get rid of all carpets. Use an air purifier with a HEPA (High Efficiency Particulate Air) filter to clean the air. People with nasal allergies to animals should limit their contact with these animals. It is the animal's dander (skin flakes) that causes allergies, not the hair length. People who are allergic to pollen and mold should use an air conditioner as much as possible. When you open the windows in your house, you let in pollen and mold spores. Ask your doctor or healthcare professional for more tips on how to allergy-proof your home.

## WHERE CAN I GET MORE INFORMATION?

For more information, contact our customer service at 1-800-323-0000.

Store between 20°-25°C (68°-77°F). Protect from light.

USE ONLY IF BODY SEAL IMPRINTED
WITH "Protective Seal" AND
YELLOW IS INTACT.

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ET397 XO50339 REV. 6/01-02 FDA4



# Cromolyn Sodium Nasal Solution USP

Nasal Allergy Symptom Controller

**NASAL SPRAY** 

**PUL** -3 200 APPROVED

FOR USE IN THE NOSE ONLY

Prevents and Relieves Nasal
Allergy Symptoms

## WHAT MAKES CROMOLYN SODIUM NASAL SOLUTION UNIQUE?

#### **Nasal Allergy Symptom Prevention**

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- No "rebound" nasal congestion
- Non habit forming
- Safe to use with other medicines, including other allergy medicines
- Safe to use throughout your allergy season
- Good for year-round allergies
- Safe for children as young as two years old

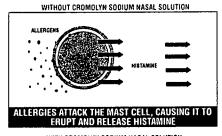
# WHAT CAUSES NASAL ALLERGY SYMPTOMS?

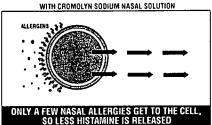
Nasal allergies are caused by airborne pollens from trees, grasses or ragweed, and by mold, animals and dust. Exposure to these nasal allergy-causing substances may cause mast cells in your nose to release histamine. When histamine is released it causes nasal allergy symptoms: sneezing, runny/itchy nose, and allergic stuffy nose.

# HOW DOES CROMOLYN SODIUM NASAL SOLUTION WORK?

Cromolyn Sodium Nasal Solution is neither an antihistamine nor a decongestant nor a corticosteroid.

It's a nasal mast cell stabilizer. In addition to treating nasal allergy symptoms, it decreases the allergic reaction by reducing the release of histamine, the trigger of allergy symptoms, from mast cells.





# HOW DO I TELL IF IT'S AN ALLERGY OR A COLD?

Some nasal allergy symptoms may seem like cold symptoms. There are several clues that you're suffering from nasal allergy symptoms. instead of a cold. Colds are caused by viral infections, and symptoms often include fever, body aches, discolored nasal discharge, or cough. It is rare for nasal allergies to produce these symptoms. If you have them, please call your doctor before beginning Cromolyn Sodium Nasal Solution. Nasal allergy symptoms include runny/itchy nose, sneezing and stuffy nose. Seasonal allergies occur the same time each year, and are linked to plant pollens,

spores, or molds. Some allergies occur year round, and may be connected to microscopic particles in common household dust, animal dander, or indoor molds. Cromolyn Sodium Nasal Solution can help you with the nasal symptoms of allergy.

# WHO SHOULD USE CROMOLYN SODIUM NASAL SOLUTION?

Cromolyn Sodium Nasal Solution is suitable for most people with nasal allergies including children as young as 2.

Cromolyn Sodium Nasal Solution is safe to use if you are taking other medicines, even other allergy medicines, because Cromolyn Sodium Nasal Solution does not cause any known drug interactions.

Don't use Cromolyn Sodium Nasal Solution if you are allergic to the ingredients. If Cromolyn Sodium Nasal Solution causes irritation to your nose, discontinue use.

## HOW TO USE CROMOLYN SODIUM NASAL SOLUTION

Begin use 1-2 weeks before you are exposed to nasal allergens.

To prevent nasal allergy symptoms, start using Cromolyn Sodium Nasal Solution before you think your symptoms will begin. Use your experience as a guide. For example: if you are allergic to cats, start Cromolyn Sodium Nasal Solution one week before you visit a house with cats. If you can't predict your allergy season, begin Cromolyn

Sodium Nasal Solution at the first signs of nasal allergy symptoms. Cromolyn Sodium Nasal Solution also relieves nasal allergies while it builds full protection against further symptoms.

Use Cromolyn Sodium Nasal Solution 3-4 times a day, every day while in contact with the cause of your nasal allergy, whether you have symptoms or not. Spray once in each nostril in the morning, at noon, at dinner, and at bedtime. Some people may get brief nasal stinging and/or sneezing right after use of Cromolyn Sodium Nasal Solution.

Full protection may take as long as 1-2 weeks with regular use so continue using Cromolyn Sodium Nasal Solution during that time. Regular use is important to achieve full protection.

# Use Cromolyn Sodium Nasal Solution throughout your allergy season.

Cromolyn Sodium Nasal
Solution can be used safely up
to 6 times a day, for up to 12
weeks. If you need Cromolyn
Sodium Nasal Solution beyond
12 weeks, speak to your doctor.
Also speak to you doctor if
your symptoms worsen, new
symptoms occur, or symptoms
do not begin to improve within
two weeks. Your symptoms
may indicate some other
underlying condition.